

## Experience with an online prospective database on adolescent idiopathic scoliosis: development and implementation

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**Abstract** Considerable variability exists in the surgical treatment and outcomes of adolescent idiopathic scoliosis (AIS). This is due to the lack of evidence-based treatment guidelines and outcome measures. Although clinical trials have been extolled as the highest form of evidence for evaluating treatment efficacy, the disadvantage of cost, time, lack of feasibility, and ethical considerations indicate a need for a new paradigm for evidence based research in this spinal deformity. High quality clinical databases offer

an alternative approach for evidence-based research in medicine. So, we developed and established Scolisoft, an international, multidimensional and relational database designed to be a repository of surgical cases for AIS, and an active vehicle for standardized surgical information in a format that would permit qualitative and quantitative research and analysis. Here, we describe and discuss the utility of Scolisoft as a new paradigm for evidence-based research on AIS. Scolisoft was developed using dot.net platform and SQL server from Microsoft. All data is

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deidentified to protect patient privacy. Scolisoft can be accessed at [www.scolisoft.org](http://www.scolisoft.org). Collection of high quality data on surgical cases of AIS is a priority and processes continue to improve the database quality. The database currently has 67 registered users from 21 countries. To date, Scolisoft has 200 detailed surgical cases with pre, post, and follow up data. Scolisoft provides a structured process and practical information for surgeons to benchmark their treatment methods against other like treatments. Scolisoft is multifaceted and its use extends to education of health care providers in training, patients, ability to mine important data to stimulate research and quality improvement initiatives of healthcare organizations.

**Keywords** Scolisoft · Clinical database · Adolescent idiopathic scoliosis · Spinal deformities

## Introduction

The success of surgical treatment of adolescent idiopathic scoliosis (AIS) is based on several factors like surgical approach, levels of fusion, operative morbidity etc. [9]. However, there is a clear lack of consensus regarding these factors, leading to variability in the treatment of outcomes in AIS [2]. This is perpetuated by lack of evidence-based approach to surgical treatment of this spinal deformity [7, 17–19]. In order to improve success of spinal surgery, we need to know what factors increase a patient's risk of complications, and which surgical procedures have the most successful outcomes.

Evidence-based approach to medical treatment received much attention during the last two decades as noted by publication of thousands of articles in medical journals on this topic. The most well accepted source of evidence is medical literature based on randomized clinical trials which are considered gold standard because of their ability to reduce the risk of biases. Much progress has been made through evidence-based approach in medicine. However, survey of literature shows that practice of evidence-based surgery is limited [1]. A recent review reported that only 3.4% of all publications in leading surgical journals are RCTs [22]. This is because surgery involves a complexity of variables and efficacy investigations because of the procedure itself. Study quality items like blinding, comparison of operative and non-operative procedures, comparison with placebo etc., are difficult and sometimes not possible in the clinical setting. Furthermore, surgical procedures are not standardized as they evolve continuously as surgeons overcome the learning curve and gain expertise [13]. Conduct of RCTs in surgery is also restricted by ethical concerns [15, 21]. In addition, it has been shown that financial support for surgical research is

limited and not much interest prevails in funding surgical trials [20].

Another method gaining popularity in evidence-based approach is systematic reviews. This is because published systematic reviews use objective methods, consistent study variables across studies, leading to transparency of results that are of wider generalizability [8, 12]. In addition, systematic reviews help surgeons gain a quick overview on the current state of science [20]. However, surgeons are still required to critically appraise large amount of information as not all systematic reviews are methodologically sound [1, 11]. In addition, the information on systematic reviews has to be correlated with clinical data and one's own experience in decision making which can be difficult in a busy practice setting.

In the recent years, high quality clinical databases (HQCD) have been found to offer an alternative approach to practice of evidence-based medicine [4, 14, 16, 25]. These databases are well recognized for their potential in bringing research closer to practice [3]. A major success story is that of the Society of Thoracic Surgeons (STS) database, which is acknowledged by other specialties, government, and third party payers as the gold standard clinical data analysis registry [23]. The STS database has over 2.7 million patient records that have contributed to the development, evaluation, and improvement of quality of care and establishment of evidence-based guidelines and risk assessment in thoracic surgery. Benefits of HQCD include high multicenter participation in data collection, generalizability of results [6], cost-effectiveness, and ability to collect large sample of cases for generating statistically significant conclusions [23].

In recognition of the fact that AIS has so far not benefited from evidence-based research and that surgical treatment guidelines and outcome measures are lacking, we developed an international high-quality clinical database, Scolisoft<sup>®</sup> to warehouse surgical cases of AIS. It is our belief, that by contributing their cases to the database, surgeons take up the role of information gatherers and contribute collectively to advancement in the area of AIS.

In this paper, we describe Scolisoft<sup>®</sup> database, its uses, and its potential in evidence-based approach to treatment of AIS.

## Methods

### Development of database concept

The concept of spinal deformity database, Scolisoft began with the idea of developing a tool that can enable the collection and retrieval of clinical parameters pertaining to surgical cases of AIS. The impetus for the development of

**Table 1** Data variables that are needed to be entered in Scolisoft

Images	
<i>Radiographs</i> (First time case entry)	Anterior posterior (AP), lateral, right side bending, left side bending, or traction, fulcrum, and push prone
<i>Radiographs</i> (Follow-up entry)	AP, lateral views
<i>Clinical photos</i> (All entries)	Anterior, posterior, lateral, and rib
Basics	Year of birth, age at surgery, sex, previous surgery, and Physician status (Active, candidate, International)
Diagnosis	Type of Scoliosis (Idiopathic, degenerative, neuromuscular, congenital, post traumatic, and other); Risser Stage (0,1,2,3,4,5 NA—Adult) Neurological Injury (Yes, No); Secondary Diagnosis (No, Yes)
Surgical procedure	Days in hospital, operative time, blood loss, revision procedure (yes, No), direct neural decompression (Yes, No), Electrophysiological monitoring (Yes, No), Fusion (No, Yes)—If yes, category (Anterior only, anterior and posterior(same day ± posterolateral), Posterior (interlaminar/facet only), Posterolateral (±posterior only), TLIF, TLIF and posteriolateral (±posterior), TLIF and posterior, PLIF, PLIF and posterolateral (±posterior), PLIF and posterior. Osteotomies (none, pedicle subtraction/decancellation, Smith-Peterson, Anterior discectomy/corpectomy, three column resection) Stage Procedure (No, Yes. 1st of two stages, 2nd of 2 stages), Bone grafts (Iliac crest, local, allograft, rib, demineralized bone matrix, substitute, BMP), Minimal invasive surgery performed (No, thoracoscopy, Laparoscopy, Mini-open (with or without microscope) other), Instrumentation (Synthes, Medtronic, Depuy, Zimmer, Stryker, other, NA), Implants (cervical: C1–C7,Thoracic: T1–T12, Lumbar: L1–L5, Material: No, Yes titanium, extra hard titanium, stainless steel and other.
Primary curves secondary curves & tertiary curves	Level (cervico-thoracic, thoracic, thoraco-lumbar, lumbar), side (left, right), apex (cervical, thoracic, lumbar), Top end vertebra (cervical: C1–C7, Thoracic: T1–T12, Lumbar: L1–L5) Bottom end vertebra (cervical: C1–C7, Thoracic: T1–T12, lumbar: L1–L5), Stable vertebra (T6–L5),Cobb angle, side bending angle, Traction Cobb angle (Not needed if side bending is entered), fulcrum bending angle, push prone angle
SRS-30 Questionnaire	Preop, postop, and follow-up questionnaire responses

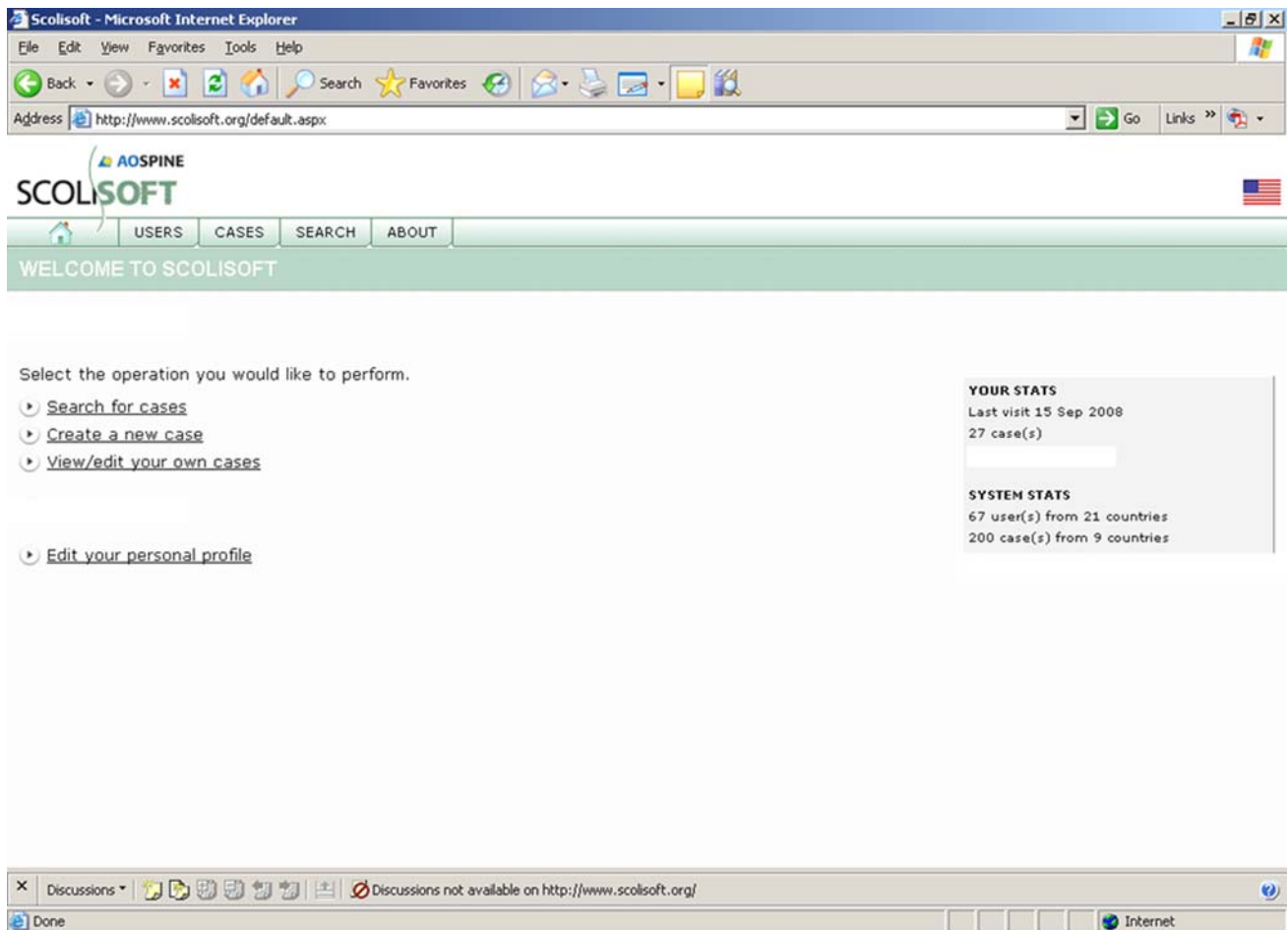
the database was initiated from the Division of Scoliosis and Spine Surgery at the University of Virginia. The concept and initial goals were developed by the Principal author. The goals were (a) To develop and establish an international online database of surgical cases of AIS (b) To make surgical data collected in the database available for clinical research for developing treatment guidelines and outcome measures for AIS. The goal of making the database international through the World Wide Web was considered the most essential feature of the database. This feature was envisioned to enable contributions to the database from larger number of surgeons internationally that will not be possible from a single institution and to capture treatment variability that will significantly aid in the development of surgical treatment guidelines and outcome measures for AIS. Scolisoft database is financed and run under the auspices of AOSpine International and can be accessed at the URL: [www.scolisoft.org](http://www.scolisoft.org). It can also be accessed directly from AOSpine website at URL: [www.aospine.org](http://www.aospine.org). Participation in Scolisoft at this point is voluntary and does not involve any associated fee. However, registration is mandatory to participate in Scolisoft database. A Steering Committee, consisting of three senior authors makes important decisions on the functioning of the Scolisoft database. Through conference calls and in-person meetings, the Committee makes important decisions on the policies and directions to take with the database; recommends priorities; and establishes quality control

methods. In addition, the Committee also decides on cases to be published, data utilization for research, and publication of research results in journals.

The process of establishing variables to be entered into the database started with the review, classification and prioritization of goals of surgical planning and implementation. For example, surgical planning of AIS includes classification of the curve (Lenke Type 1, 2, 3 etc...), bone maturity (Rissers sign), Cobb angle, curve flexibility, age of the patient, menarche onset etc. In addition, variables deemed important for evaluation of surgical procedure like complications, type of instrumentation used, number of days in hospital, SRS morbidity and mortality dataset, SRS quality of life questionnaire responses etc... were also included. Variables are arranged so that the order of occurrence coincides with the progression of a typical surgical patient visits, i.e., pre-op, post-op and follow up. Table 1 shows the list of variables that are to be entered for each case into Scolisoft.

#### Database development and implementation

The database was developed using the dot.net platform and SQL server from Microsoft. To address the possibility of high user volume, a robust server architecture was implemented. This included the use of a server to store the database, which would be accessed by registered users internationally via the World Wide Web. Elements that



**Fig. 1** Figure showing the three main functions of Scolisoft—Search for cases, Create a new case, and View/edit your own case (*bold red arrow*)

were considered important are the network server, database structure, security, ease, time-efficient data access, and possibility to enter various types of data in different formats. To accommodate the aforementioned requirements, Scolisoft was designed as a multidimensional, relational database. The multidimensional feature allows for entry of a broad range of data in diverse formats including radiographs, photos, MRI, CT scan, and text. The relational feature of the database allows for data entry, editing, updates, deletions, data retrieval, summarization, and reporting. In addition, the system has been structured with a querying system that facilitates easy retrieval of information (Fig. 1). For example, a researcher can obtain detailed pre and post surgical and follow-up information on a case of interest or a group of similar curves [thoracic curve, right side, T9 apex with end vertebra at T5, T12, Cobb angle range 55–60° (Fig. 2). Figure 3 shows an overview of the data collection and entry into Scolisoft Database.

No separate installation program is required by each user as the database is available on the World Wide Web.

The system is developed to provide a consistent and intuitive user interface with error recovery features when conflicting or incomplete information is submitted to the database. For example, an imported radiograph from Picture Archiving Communication System (PACS) in a reversed position can be set right or mirrored and cropped with the tools available in Scolisoft. Magnification of each radiograph allows it to appear in full screen on the computer so that the Cobb angle calculation tool can be used. Similarly, the user can track the completeness of the data entered (Fig. 4).

Data visualization in Scolisoft offers an efficient system of getting a quick overview of each case. The system can be used during real clinical tasks to help surgeons evaluate the surgical procedure performed on a patient at any setting—be it in the clinic or operating room. Scolisoft is designed to display not only pre or post surgery radiographs and clinical photographs of the patients, but different time series (pre, post surgery and all the follow-up visits) as well, side by side different cases on a single

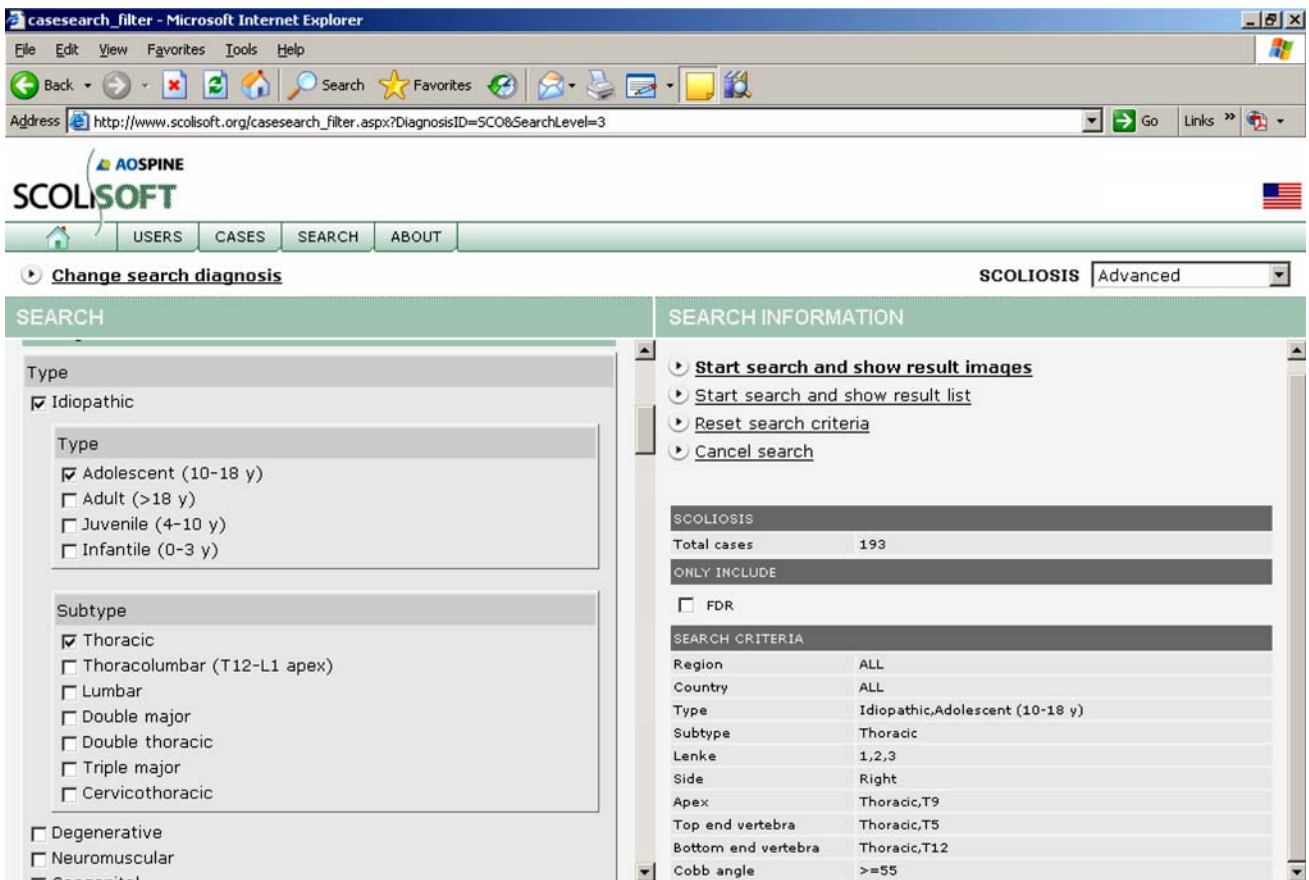
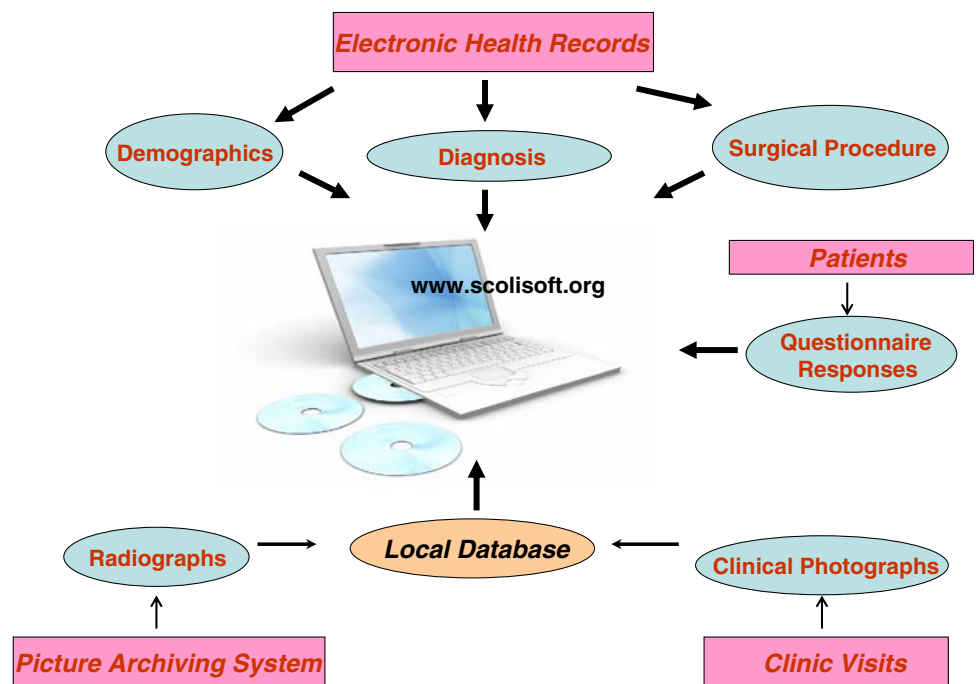


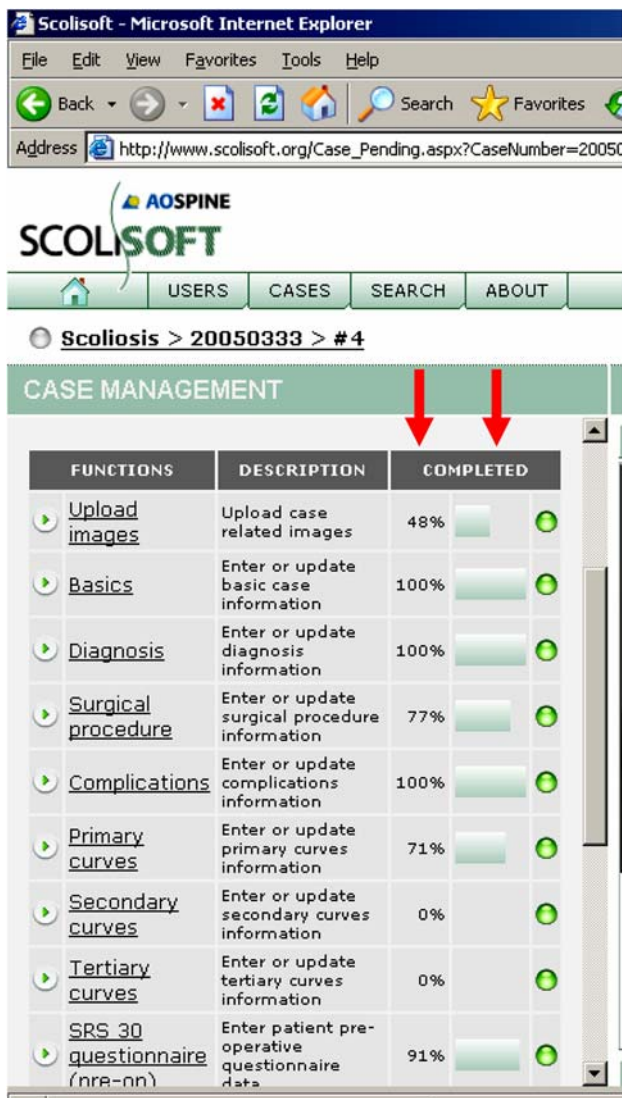
Fig. 2 Figure showing data querying form in Scolisoft

Fig. 3 Overview of data collection and entry into Scolisoft



screen to allow comparisons. The default screen displays all the cases with X-rays and photographs. This can be customized to a specific interest (i.e., display of only the

preop and last follow-up X-rays and photographs). This facilitates a complete overview of a case at a glance to make quick decisions and eliminates the time consuming



**Fig. 4** Figure showing data completion indication on Scolisoft (*bold red arrows*)

accessing of different screens to visualize results of surgery. In addition, the database has the capability of generating a detailed report of data entered on each case. The report is comprehensive including both images and text and can be printed out in both PDF and html formats.

The querying system at the front end of Scolisoft permits entry of a number of variables including range of Cobb angles, diagnosis, and surgical to retrieve treatment of similar curves by different surgeons. Figure 5 shows an overview of treatment variability in left thoracolumbar curves with an apex at T12, T12–L1, and with a Cobb angle range of 40–50° treated with anterior surgery. The software retrieves five cases of fairly identical curves out of the 200 cases stored in the database. It can be seen that these cases were treated in slightly similar fashion with anterior construct ranging from 4 to 6 vertebrae and one or

two rods. From this overview, it is possible to analyze at a glance the results of anterior surgery of similar curves. After mining such a query, one can also look at other parameters such as cosmesis or days in the hospital etc... in the case reports.

Scrolling further down the screen, it is possible to have an evaluation of the clinical photograph of the patient before and after (Fig. 6). Interestingly, one can notice that the only patient who has unbalanced shoulders post operatively (fourth patient from the left), also had it preoperatively. Further follow up clinical photographs of this patient (not shown) showed that the shoulder regained the balance over time. In this scroll down menu, it is possible to display the lateral X-rays to appreciate the sagittal profile or the forward bending clinical photograph to appreciate the rib hump.

#### Regulatory issues

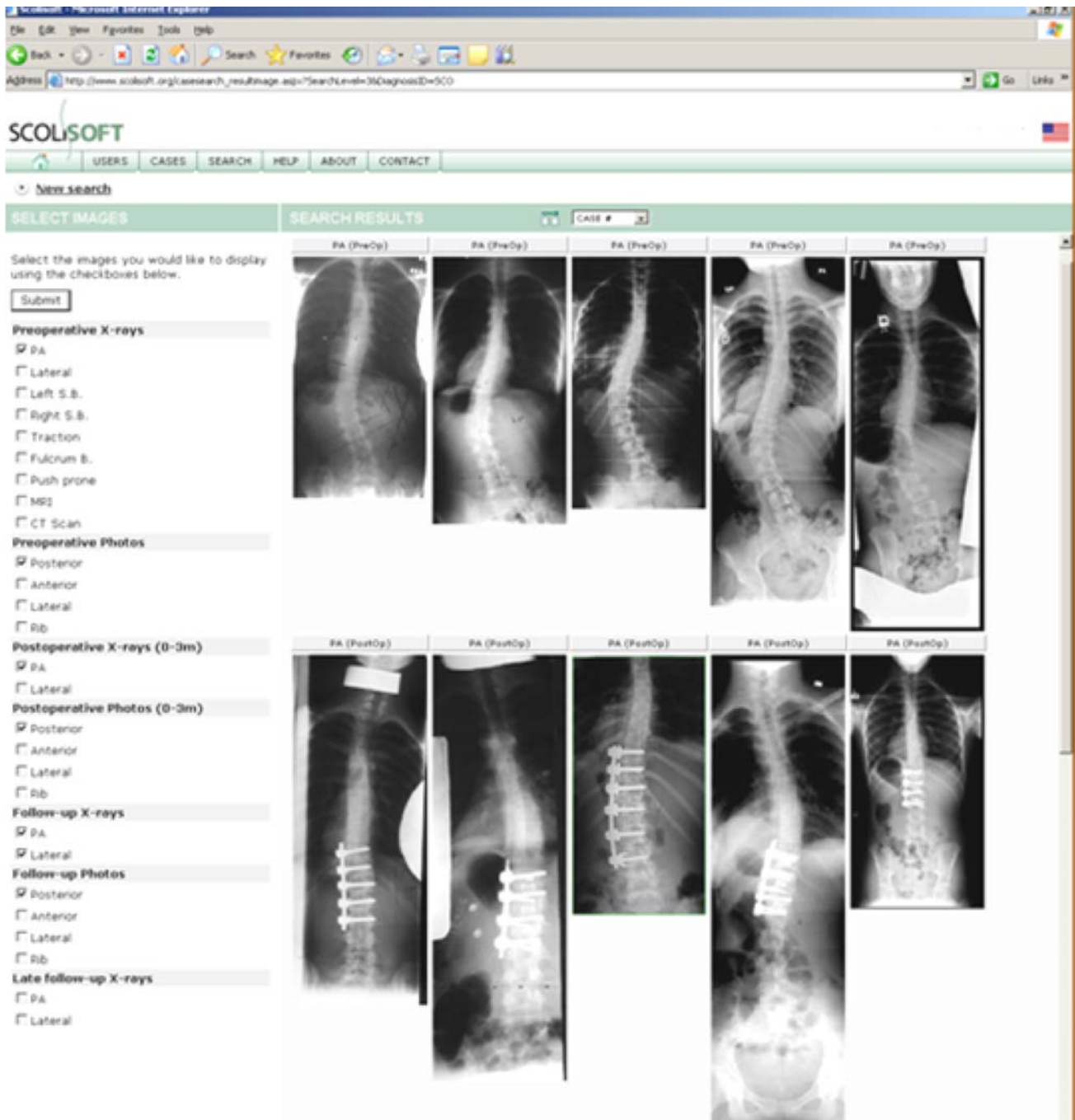
The University of Virginia Institutional Review Board has given approval for the use of Scolisoft software as a tool for the database in 2006. Because the current protocol is a database warehousing deidentified data, informed consent has been waived.

#### Privacy and confidentiality

Entry into Scolisoft database is double-password protected. Each case is given a case identification code after entry into the database. This enables linking of information in the database to the identities of the subjects for purposes of verifying entries and adding additional follow-up data. Under no circumstances are full names or any other HIPAA identifiers (address, date of birth, admission date, date of death, telephone or Fax numbers, devise identifiers, biometrics, full face photographs or any other identifying numbers that is derived from or related to the information of the individual) are included. All data entered into the database will be deidentified. Registered users can use the data in the database for research purposes after an IRB approval of the study protocol from the individual institution and permission from AOSpine International is obtained.

#### Data entry

Scolisoft software is operationally straightforward and simple. Data can be entered by study nurses or coordinators with a minimal training. Point-and-click approach with dropdown boxes for diagnoses, surgical procedures, complications, preselected values for diagnosis, surgical procedures, primary, secondary, and tertiary curves maintain data integrity and eliminate “free text” entries. Such a

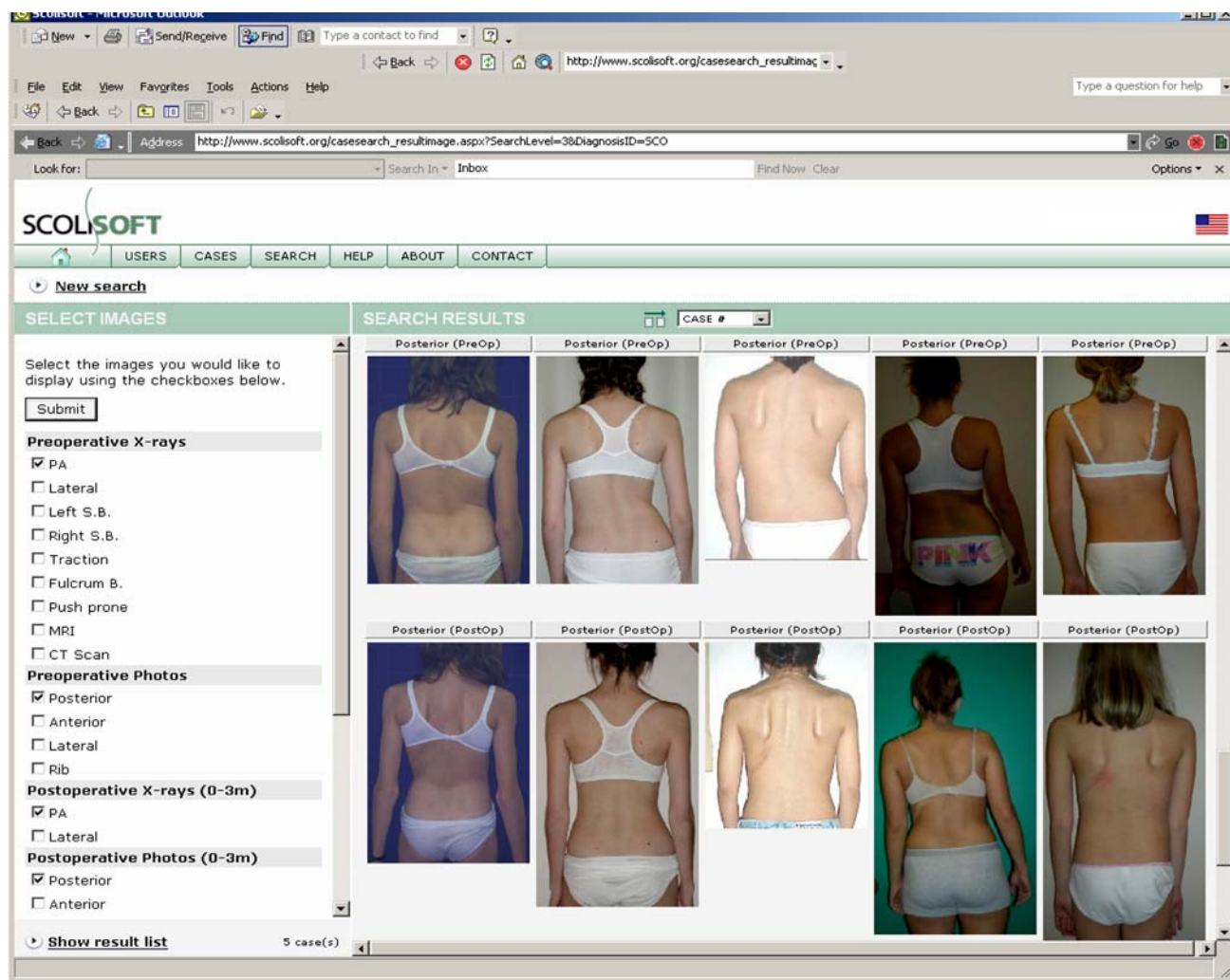


**Fig. 5** Screen with series of radiographs showing variation of level selection for similar curves treated with anterior surgery

system minimizes the time spent on data entry, reduce redundancy in data entry and assures accuracy. However, it is not possible to completely eliminate free text entry. Typically, the time taken to enter data depends upon whether it is the first time entry of case data or follow-up. First time (pre surgical) data entry takes on an average 30–35 min as it involves import of all the radiograph images required for surgical planning, clinical photographs, diagnosis, surgical procedures, complications, primary,

secondary and tertiary curves, and SRS-30 questionnaire responses. The follow-up data entry after each visit then on will require on an average, 15–20 min, involving import of AP and lateral radiographs, clinical photographs and SRS-30 questionnaire responses.

Scolisoft uses standardized software in order to achieve consistent and uniform data collection which helps maintain the quality of the database. Some or all the data can be entered into the database by study nurses or coordinators



**Fig. 6** Screen with series of clinical photographs before and after surgery of the same patients whose radiographs were shown in figure

with medical background and training in Scolisoft software.

#### Database quality control plan

To optimize data quality, we developed a quality control plan for our database. Quality control is defined as activities that are performed during and after data collection. The goal of these activities is to identify and correct data errors.

To assure standardized data collection, Scolisoft utilizes standardized software to achieve consistent and uniform data collection. Preselected values were established for diagnosis, surgical procedures, primary, secondary and tertiary curves to maintain data integrity and eliminate “free text” entries and data errors. Data checks and corrections are made by each registered user at the time of data entry. All cases submitted to Scolisoft are reviewed by the senior author. Detection of data errors is also achieved

through review of each case submitted for quality of images, completeness, proper documentation, and conformity to privacy and HIPAA guidelines. Only those cases that conform to the aforementioned criteria are published in the database. Cases with poor quality images and incomplete data etc., are sent back to the submitter with a list of specific changes needed, to have the case published in Scolisoft. If the required data on the case sent back could not be provided by the investigator, the case is rejected and not published in the database.

#### Results

Scolisoft Database currently has a membership of 66 users from 19 countries. Participating countries include: USA, India, China, UK, Netherlands, France, Germany, Italy, Finland, Argentina, Brazil, and Venezuela. To date, the database consists of 200 detailed cases of AIS with follow-



up data and cases are continually being submitted to be published in the database.

Cases entered into Scolisoft served well in patient education at our institution. Patients and families were shown radiographs and clinical photographs of cases that had curve characteristics similar to theirs' to aid in decision making process for preparation for surgery. In addition, reports of these patients whose data have been entered into the database before and after surgery and during follow-up visits were shown to them to educate them on their treatment process. Efforts are underway to assess the use of Scolisoft as a health care technology tool in patient satisfaction.

One of the major problems encountered in Scolisoft database is the incompleteness and inaccuracy of data submitted, resulting in extra time involved in data entry. These data usually included Cobb angle, stable vertebrae, and data on primary and secondary curves (curve apex, end vertebrae). The problem is solved by obtaining the required parameters from the radiographs entered into Scolisoft, which can be enlarged and measured using the measurement tools available in Scolisoft during the review process. These changes required in the values may be edited and corrected before online publication if the values are judged to be inaccurate. Such incompleteness and inaccuracies result in extra time consumption, but we believe it is important for the quality, the integrity and the consistency of the database. In addition, several surgeons complained about the number of fields that need to be filled and time involved. Despite this, there have been several surgeons who contributed to the registry with complete and detailed surgical cases of AIS. Currently surgeons are not required to fill in the curve characteristics (curve type, Cobb, Apex...) from the radiographs as they are done during the review and editing process. This saves an enormous time to the submitting surgeon.

Data collected in Scolisoft has been used in two separate studies that were published [2, 15] In addition, the data is being used in an ongoing, funded study comparing instrumentations used in the treatment of AIS.

Cases of various curve characteristics that have been entered into Scolisoft have been used routinely at our institution for teaching residents and fellows who have limited experience doing actual surgeries on AIS. We are also in the process of evaluating Scolisoft as a technology for educating health care professionals.

## Discussion

We demonstrate the creation and use of an international, online clinical database on surgical cases of Adolescent Idiopathic Scoliosis.

Clinical databases as a paradigm for evidence based medicine has been well documented [3, 4, 10]. The strength of HQCD is that, data stored in them is generalizable, can be shared among surgeons internationally, reflects what happens in the real world, and is not inferential [14, 24].

Scolisoft has been developed to create a new environment of shared learning among spine surgeons through their contribution of surgical cases to a common pool. Several surgeons both national and international have shown keen interest in the database through contribution of their cases and continue to do so. Collection of large amount of data can be of enormous value in establishing evidence-based guidelines and producing change in observed outcomes [5].

The advantages of Scolisoft are clear. First, the use of the World Wide Web offers an ideal platform for shared learning as health care professionals can access accurate clinical data from anywhere, any time, and under any setting from the database. Besides, the World Wide Web is familiar to many users and does not require any special software installation or maintenance. A selection of surgical cases is available at the finger tips for benchmarking and research through the database. Most surgeons work on a continuous quality improvement mode. They try to advance their knowledge and performance by critically examining the outcome of every surgical procedure they perform. Scolisoft provides an added resource for their continuous quality improvement efforts by providing data on surgical procedures by other surgeons, and an opportunity for gauging their performance against others, which would not have otherwise been possible.

Secondly, the simple system of case identifier used as a personal identifier disguise adopted in Scolisoft offers practical solution to the problem of patient confidentiality. In addition, the double password system adopted prevents access to data by other users while the case is in the view edit mode.

Currently however, it should be noted that the data stored in Scolisoft are sparse for some purposes. For example, statistical analysis of data is currently not available. However, efforts are underway to generate total and domain scores for SRS-30 patient questionnaires before and after surgery and follow-up along with other analytical capabilities. With such a system, we anticipate that the database will be better equipped for clinical research and benchmarking of surgical cases.

In summary, the Scolisoft Online Database, unlike other databases, is multifaceted as its use extends to education of young surgeons, patient education, ability to mine important data to stimulate research, and quality improvement initiatives of healthcare organizations.

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